



Virginia Department of
Health Professions
Board of Pharmacy

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APPLICATION FOR A NON-RESIDENT OUTSOURCING FACILITY REGISTRATION

Check Appropriate Box(es):

New \$350.0 Reinstatement Call Board Change of Tradename* No Fee
 Change of Ownership \$65.00 Change of VA PIC* No Fee Change of Address* No Fee

**Application fees are not refundable. Applications are valid for one year from the date of receipt.
 The required fees must accompany the application. Make check payable to "Treasurer of Virginia".
 Additional documentation not required for change of PIC or change of ownership applications.**

Applicant—Please provide the information requested below. (Print or Type) Use full name, not initials.			
Name of Outsourcing Facility		Telephone Number	
Street Address		Fax Number	
City	State	Zip Code	
Resident State Permit Number(s) to practice as Outsourcing Facility		*Effective Date of Change	
FDA Registration Number as Outsourcing Facility		Email Address of Virginia Pharmacist-in-Charge	
Virginia Non-Resident Outsourcing Facility Registration Number, if applicable: 0236-		Virginia Non-Resident Pharmacy Registration Number, if applicable: 0214-	
Designated Virginia licensed pharmacist-in-charge:			
Print Name: _____		License No.: 0202-	
By affixing my signature I acknowledge that I am responsible for this outsourcing facility's compliance with the Virginia Drug Control Act and am fully engaged in the compounding performed at the location stated on the application.			
Signature: _____		Date: _____	

FOR OFFICE USE ONLY: <input type="checkbox"/> Sterile Compounding <input type="checkbox"/> Non-Sterile Compounding				
Date processed:	Check No:	Receipt No:	Application No:	
Date Issued:	Registration Number 0236-	Reviewed By:	Date Reviewed:	USP or cGMP:

OWNERSHIP TYPE—check one: Corporation Partnership Individual Other

Name of ownership entity if different from name of application: _____

Street Address: _____ Phone No. _____

City: _____ State: _____ Zip Code: _____

State(s) of incorporation: _____

List all other trade or business names used by this facility

Name: _____

Name: _____

Name: _____

Name: _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED

Name: _____ Title: _____

Contact Address: _____

Name: _____ Title: _____

Contact Address: _____

Please answer the following questions:

1. Does the outsourcing facility engage in the compounding of **STERILE** drug products? Yes No

4. Does the outsourcing facility engage in the compounding of **NON-STERILE** drug products? Yes No

2. Has the outsourcing facility been issued a warning letter by the FDA within the past 2 years? **If yes, please provide a copy of the warning letter and related facility responses.** Yes No

4. Has the outsourcing facility issued any recalls for compounded products within the past 2 years, either voluntary or directed by the FDA? Yes No

5. Does the outsourcing facility dispense compounded drugs pursuant to valid prescriptions? **If yes, a non-resident pharmacy registration is also required.** Outsourcing facilities that share the same space with a pharmacy must perform all compounding in compliance with cGMPs. Yes No

ADDITIONAL REQUIRED INFORMATION: The requested documentation must be submitted with the application.

1. A legible copy of this facility's current, unexpired, unrestricted permit(s) in its resident state authorizing the practice as an outsourcing facility.
2. A legible copy of this outsourcing facility's current, unexpired, unrestricted FDA registration.
3. A copy of the current FDA outsourcing facility inspection report, conducted no more than 1 year prior to the date of submission of this application, in compliance with §54.1-3434.5 of the Virginia Drug Control Act and indicating compliance with current good manufacturing practices (cGMPs). Corrective action addressing any identified deficiencies must be submitted with the inspection report, along with any correspondence with a regulatory body regarding the corrective action.
4. A listing of all states in which the outsourcing facility is licensed including the state license number.

*** If the outsourcing facility is changing trade name or address, the current resident state license for the outsourcing facility reflecting the updated information must be submitted with the application.**